




Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.	E321744-D1002-1-ULCB
Date of issue	2015-10-29
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CB Testing Laboratory	UL Camas
Address	2600 N.W. Lake Road, Camas, WA, 98607, USA
Applicant's name	XP Power LLC
Address	15641 Red Hill Ave., Suite 100 Tustin, CA 92780 USA
Test specification:	
Standard	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure	CB Scheme
Non-standard test method.....	N/A
Test Report Form No.....	IEC60601_1J
Test Report Form Originator	UL(US)
Master TRF	2014-07
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Test item description:	Component Power Supply intended for Building-in	
Trade Mark:	"XP"	
Manufacturer:	Same as Applicant	
Model/Type reference:	EPL225PSXX (where XX can be any number between 12 and 48 designating the output voltage, may also be provided with suffix "SF"	
Ratings:	Input: 100-240 Vac, 50/60Hz, 3A Max.; Output: See Model Differences for details	
Testing procedure and testing location:		
<input type="checkbox"/> CB Testing Laboratory:		
Testing location/ address:	UL Camas 2600 N.W. Lake Road, Camas, WA, 98607, USA	
<input type="checkbox"/> Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name + signature):		
Approved by (name + signature):		
Testing procedure: TMP/CTF Stage 1:		
Testing location/ address:		
Tested by (name + signature):		
Approved by (name + signature):		
Testing procedure: WMT/CTF Stage 2:		
Testing location/ address:		
Tested by (name + signature):		
Witnessed by (name + signature):		
Approved by (name + signature):		
Testing procedure: SMT/CTF Stage 3 or 4:		
Testing location/ address:	XP Power Ltd. 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598 SINGAPORE	
Tested by (name + signature):	Chin Chee Siang	<i>Chin Chee Siang</i>
Witnessed by (name + signature):		
Approved by (name + signature):	Ron Nabong	<i>Ron Nabong</i>

Supervised by (name + signature):	Timothy L. Gambrell	
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List of Attachments (including a total number of pages in each attachment):

Refer to Appendix A of this report. All attachments are included within this report.

Summary of testing

Tests performed (name of test and test clause):

Testing location:

Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.

Summary of compliance with National Differences

List of countries addressed: Austria, Korea, Republic of, USA, Canada, United Kingdom, Sweden

[X] The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint).

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Refer to the enclosure(s) titled Marking Plate in the Enclosures section in Appendix A of this report for a copy.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of Installation and Use:	For Building-in
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location):	The models covered in this report are component AC-DC power supplies intended for use in Medical Equipment. They are open frame power supplies intended for building-in.
Mode of Operation:	Continuous
Supply Connection:	For Bulding-in
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s)	2014-11-14, 2015-05-28, 2015-09-18
Dates tests performed	2015-04-14 to 2015-05-14, 2015-09-30
Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement.....	Pass (P)
- test object was not evaluated for the requirement	N/E
- test object does not meet the requirement.....	Fail (F)
Abbreviations used in the report:	
- normal condition: N.C.	- single fault condition: S.F.C.
- means of Operator protection: MOOP	- means of Patient protection: MOPP
General remarks:	
"(See Attachment #)" refers to additional information appended to the report.	
"(See appended table)" refers to a table appended to the report.	
The tests results presented in this report relate only to the object tested.	
This report shall not be reproduced except in full without the written approval of the testing laboratory.	
List of test equipment must be kept on file and available for review.	
Additional test data and/or information provided in the attachments to this report.	
Throughout this report a point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1:2012	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided	Yes
When differences exist; they shall be identified in the General product information section.	

Name and address of factory (ies): XP POWER (KUNSHAN) LTD
 230 Bin Jiang Nan Rd., Zhangpu Town, Kunshan
 Jiangsu 215321 China

ABES TECHNOLOGY CO. LTD.
 3 LANE 891, SEC 1 SHANGSHUI RD.
 XIUSHUI HSIANG
 CHANGHUA HSIEN 504 TAIWAN

GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.

Refer to the Report Modifications page for any modifications made to this report.

Product Description

The models covered in this report are component AC-DC power supplies intended for use in Medical Equipment. They are open frame power supplies intended for building-in.

Model Differences

All models in the Model EPL225PSXX Series are identical with exception to the Mains Transformer (TR1) and minor secondary components that allow for different output voltage ratings.

Suffix "-SF" indicates single fuse provided in the line side of the primary.

Output Ratings:

EPL225PS12: V1: 10.1-13.5Vdc, 12.5A Max., 150 W Max. (Convection Cooled) or 10.1-13.5Vdc, 18.75A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS15: V1: 13.6-17Vdc, 10A Max., 150 W Max. (Convection Cooled) or 13.6-17Vdc, 15A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS18: V1: 17.1-21Vdc, 8.33A Max., 150 W Max. (Convection Cooled) or 17.1-21Vdc, 12.5A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS24: V1: 21.1-26Vdc, 6.25A Max., 150 W Max. (Convection Cooled) or 21.1-26Vdc, 9.38A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS28: V1: 26.1-31Vdc, 5.36A Max., 150 W Max. (Convection Cooled) or 26.1-31Vdc, 8.04A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS33: V1: 31.1-33Vdc, 4.54A Max., 150 W Max. (Convection Cooled) or 31.1-33Vdc, 6.81A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS36: V1: 33.1-42Vdc, 4.16A Max., 150 W Max. (Convection Cooled) or 33.1-42Vdc, 6.25A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

EPL225PS48: V1: 42.1-54Vdc, 3.1A Max., 150 W Max. (Convection Cooled) or 42.1-54Vdc, 4.69A Max., 225 W Max. (Forced Air Cooled); V2: 12Vdc, 0.5A, (Forced Air Cooled Only)

Additional Information

The required clearance values have been assessed for suitability up to 4000 m elevation (1.14 correction factor as per IEC 60664-1, Table A2).

The need for the additional testing and evaluation shall be determined in the end product investigation.

The nameplate markings provided as an Enclosure - Marking Plate are considered representative of the entire series.

The power supply series covered by this report employ Double/Reinforced Insulation between Primary and Secondary circuits.

Review of the Risk Management File was not covered under this evaluation.

Technical Considerations

- The product was investigated to the following additional standards:
EN 60601-1:2006/A1:2013, KS C IEC 60601-1, ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, BS EN 60601:2006 A1, SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014
Additional: None
- The following additional investigations were conducted: N/A
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- The following accessories were investigated for use with the product: None
- Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)
- Scope of Power Supply evaluation excludes the following: Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15; Battery related clauses: 7.3.3, 15.4.3; Hand Control related clauses: 8.10.4; Oxygen related clauses: 11.2.2; Fluids related clauses: 11.6.2 – 11.6.4; Sterilization clause: 11.6.7; Biocompatibility Clause: 11.7 (ISO 10993); Motor related clauses: 13.2.13.3, 13.4; Heating Elements related clause: 13.2
- The product is evaluated only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product was submitted and evaluated for use at the maximum ambient temperature (T_{ma}) permitted by the manufacturer's specification of: 50°C at full rated load and 70°C at 50% rated load. See the Output Ratings Table in the Model Differences section for details.

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-Secondary: 280 Vrms, 484 Vpk, Primary-Earthed Dead Metal: 240 Vrms, 400 Vpk

The power supply terminals and/or connectors are: Not investigated for field wiring

The maximum investigated branch circuit rating is: 20A

Proper bonding to the end-product main protective earthing termination is: Required

An investigation of the protective bonding terminals has: Not been conducted

The following input terminals/connectors must be connected to the end-product supply neutral: Input Connector (CN1) N terminal.

The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY2 insulation system with the indicated rating greater than Class A (105°C): TR1 (Class F)

The following end-product enclosures are required: Fire, Mechanical, Electrical

Suitable disconnect device is to be provided in the end system.

Temperature, Leakage Current with a non-frequency weighted device and Dielectric Strength testing shall be considered in the end system.

Printed Wiring Board rated 130°C.

Heatsinks are floating and considered live. They should not be accessible in the end-product.

Heating test was not conducted on unit with input/output leads. If unit is provided with input and/or output leads, then temperature on leads must be measured and cannot exceed 105°C.

This power supply has been evaluated as a continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).

The end product shall ensure that the requirements related to accompanying documents, clause 7.9, are met.

The need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation.

Models provided with suffix SF only provided with one line side fuse. Consideration should be made in the end-use product to determine the need of double pole fusing.

The suitability of the breaking capacity of the fuse per Clause 8.11.5 shall be verified in the end product.

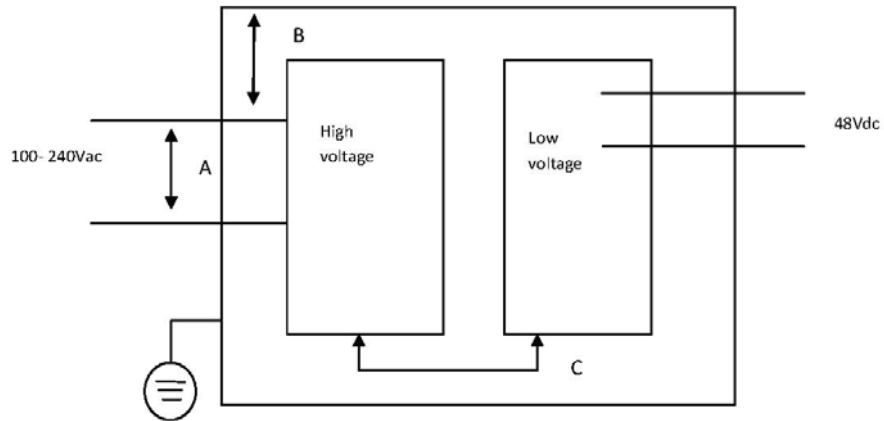
When installed in a Class II end product, the power supply shall be mounted in a manner that provides sufficient clearance and creepage distance between the hazardous parts and accessible conductive parts.

Proper bonding to the Class I end-product main protective earthing termination is required (via mounting holes on the PCB), unless for Class II applications. For Class II applications the primary side mounting pads are isolated from accessible conductive chassis by Reinforced Insulation.

This power supply was evaluated with Two MOPP between Primary and Secondary for 484Vpk/280Vrms; One MOPP between primary and Earth for 400Vpk/240Vrms.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Insulation Diagram - (01) Insulation Diagram



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

TABLE: INSULATION DIAGRAM									Pass
Pollution Degree:			2						-
Overvoltage category:			II						-
Altitude:			4000 (m)						-
Additional details on parts considered as applied parts:			[X] None [] Areas: ____ (See Clause 4.6 for details)						-
Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working Voltage V_{rms}	Working Voltage V_{pk}	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	MOOP (1)	IIIb	240	339	2.5	2.28	5.2	5.2	Between L/N of CN1
B	MOPP (1)	IIIb	240	339	4	2.85	8.1	8.1	Between L to PE terminal on PWB
C1	MOPP (2)	IIIb	280	484	8.8	7.98	9	9	Between pins of TR1; Additionally employs triple insulated wire separately certified to Annex L requirements
C2	MOPP (2)	IIIb	240	400	8	7.98	8.6	8.6	Between pins of IC3, IC4
Supplementary Information: Refer to Appendix A for the Insulation Diagram.									
<p>A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified. Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:</p> <ul style="list-style-type: none"> - All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances. - Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional - Applied parts are extended beyond the equipment enclosure and terminated with an arrow. - Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow. 									